

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

WILLIAM R. FISHER and SILBRAY)	Civil Action No. 4:09-cv-00252-TLW
N. FISHER,)	
)	
Plaintiffs,)	
)	
vs.)	<u>DEFENDANTS WYETH LLC AND</u>
)	<u>SCHWARZ PHARMA, INC.'S</u>
MARK F. PELSTRING, M.D.,)	<u>MEMORANDUM IN SUPPORT OF</u>
WYETH, INC., SCHWARZ PHARMA,)	<u>THEIR MOTION FOR SUMMARY</u>
INC., and PLIVA USA, INC.,)	<u>JUDGMENT</u>
)	
Defendants.)	
)	

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Civil Rules 7.04 and 7.05, Defendants Wyeth LLC, previously known as Wyeth, Inc. (“Wyeth”), and Schwarz Pharma, Inc. (“Schwarz”) respectfully submit this memorandum of law in support of their Motion for Summary Judgment. As explained below, both Wyeth and Schwarz are entitled to judgment as a matter of law on all claims.

INTRODUCTION

This is a products liability case in which Plaintiffs William and Silbray Fisher (“Plaintiffs”) allege that William Fisher (“Mr. Fisher”) suffered injuries after ingesting the prescription drug metoclopramide between January 15, 2003 and January 31, 2005. (Compl. ¶¶ 2, 41).¹ Plaintiffs do not claim that Mr. Fisher ingested any metoclopramide product, either brand name or generic, manufactured by Wyeth or Schwarz. Rather, Plaintiffs contend that

¹ Operating under South Carolina’s medical malpractice statute, S.C. Code Ann. § 15-79-125, Plaintiffs filed a Notice of Intent to File Suit and an expert affidavit, along with a copy of their Summons and Complaint, on May 22, 2008. However, Plaintiffs never served the Summons and Complaint on any defendant in this case. Plaintiffs filed a second Summons and Complaint on January 16, 2009, which were served on Wyeth and Schwarz on February 2, 2009. All references to the Complaint herein are to Plaintiffs’ 2009 Complaint (the “Complaint”).

Defendant Pliva U.S.A., Inc. (“Pliva”) manufactured the generic metoclopramide tablet that Mr. Fisher ingested. (Notice of Product Identification at 1 [Docket No. 64]). Nevertheless, Plaintiffs assert that, because Wyeth and Schwarz, at certain times, manufactured brand name metoclopramide (Reglan[®]), both companies can be held liable for allegedly failing to adequately warn Mr. Fisher’s doctors about the risks associated with generic metoclopramide manufactured by Pliva. Because Mr. Fisher neither purchased nor ingested metoclopramide manufactured or distributed by Wyeth or Schwarz, Plaintiffs’ claims fail as a matter of law.

Under well-established South Carolina law,² a products liability action can be sustained only against the actual manufacturer or seller of the product that caused the alleged injury. *See Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004 (D.S.C. 1981); *Baughman v. Gen. Motors Corp.*, 627 F. Supp. 871 (D.S.C. 1985), *aff’d*, 780 F.2d 1131 (4th Cir. 1986). In other words, to recover from Wyeth or Schwarz, Plaintiffs must show that a Wyeth or Schwarz product caused Mr. Fisher’s injury; neither defendant is liable for harm allegedly caused by another manufacturer’s product.

Consistent with this principle, there is no authority in the Fourth Circuit that requires a brand name manufacturer such as Wyeth or Schwarz to warn about the risks associated with the use of their competitor’s generic drug. To the contrary, the Fourth Circuit has expressly concluded that a brand name manufacturer does not have a duty to warn of the danger associated with another manufacturer’s generic drug. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171

² Plaintiffs have conceded that, at all relevant times, Mr. Fisher received medical treatment and was prescribed metoclopramide in South Carolina. (Compl. ¶¶ 18, 34). South Carolina is also the site of the allegedly tortious acts. (*Id.* ¶¶ 18-20). Accordingly, for purposes of this motion, South Carolina law is the law applicable to Plaintiffs’ claims. *See Oglesby v. GMC*, 190 F.3d 244, 251 (4th Cir. 1999) (stating that in a diversity action a federal court must apply the choice of law rules that would be applied by the courts of the state in which it sits) (citing *Klaxon v. Stentor Mfg. Co.*, 313 U.S. 487, 496 (1941)); *Lister v. NationsBank*, 329 S.C. 133, 143, 494 S.E.2d 449, 454 (Ct. App. 1997) (“Under traditional South Carolina choice of law principles, the substantive law governing a tort action is determined by the state in which the injury occurred.”).

(4th Cir. 1994) (holding that a manufacturer of a brand name drug (Wyeth) is not responsible for alleged misrepresentations where the plaintiff took its competitor's generic product) (applying Maryland law); *see also Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716, at *2 (S.D.W.V. Nov. 13, 2009) (citing *Foster* with approval and holding that Wyeth and Schwarz are not responsible for the damage resulting from a product they did not manufacture, distribute, or sell) (applying West Virginia law); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009) (following *Foster* and holding that Wyeth and Schwarz are not liable for injuries where the plaintiff took their competitors' generic product) (applying North Carolina law).

The Fourth Circuit's holding in *Foster* is consistent with the nearly unanimous authority that has addressed this issue. Thirty-five decisions in twenty different states have rejected the proposition advanced by Plaintiffs, namely that manufacturers of brand name drugs are liable, on theories of misrepresentation or otherwise, for injuries allegedly caused by the ingestion of generic drugs manufactured by other companies. Indeed, twenty-six decisions in seventeen states have already rejected similar claims against Wyeth and/or Schwarz in cases involving metoclopramide. The principles set forth in this landslide of well-reasoned and persuasive authority apply squarely to this case.

For these reasons, and those more fully set forth below, Wyeth and Schwarz respectfully request that the Court grant their Motion and enter summary judgment on all claims.

UNDISPUTED FACTS

Metoclopramide is a prescription drug approved by the FDA to treat, among other things, gastroesophageal reflux disease and certain other conditions. (Compl. ¶ 27). Metoclopramide is available in brand (Reglan[®]) and generic formulations. (Sunshine Aff. ¶¶ 2, 7, attached as Exhibit 1). At different times, Wyeth and Schwarz manufactured and distributed brand name

metoclopramide, Reglan[®]. From approximately late 1989 through late December 2001, Wyeth manufactured and distributed Reglan[®] tablets. (Exh. 1, Sunshine Aff. ¶¶ 2-3). Schwarz acquired certain rights associated with Reglan[®] tablets from Wyeth in late December 2001, and thereafter manufactured, distributed, and/or sold brand name Reglan[®] tablets until February 2008. (Exh. 1, Sunshine Aff. ¶ 3; Siefert Aff. ¶ 2, attached as Exhibit 2). Schwarz never manufactured, sold, or distributed any formulation of generic metoclopramide.³ (Exh. 2, Siefert Aff. ¶ 3). Since the mid-1980s, a number of companies, including Pliva, have manufactured and distributed generic metoclopramide. (Compl. ¶ 77; Exh. 1, Sunshine Aff. ¶ 7).

Plaintiffs allege that Mr. Fisher ingested metoclopramide manufactured by Pliva from January 15, 2003 until some time in early 2005 as prescribed by his physician, Defendant Mark F. Pelstring, M.D. (“Pelstring”). (Compl. ¶¶ 35-41 (alleging metoclopramide use between January 15, 2003 and January 31, 2005); *see also* Notice of Product Identification at 1 (stipulating to Mr. Fisher’s use of generic metoclopramide manufactured by Pliva “from January 2003 until at least April 2005”)). Thereafter, “on May 25, 2005 William Fisher was examined by Dr. Michael McCaffrey, a neurologist, who diagnosed him as suffering from drug-induced Tardive Dyskinesia related to his long-term use of Reglan/metoclopramide.” (Compl. ¶ 43).

Notwithstanding the stipulated fact that Mr. Fisher never ingested any Wyeth or Schwarz product, Plaintiffs have asserted a variety of products liability claims against Wyeth and Schwarz, including: strict products liability; manufacturing and design defects; breach of express and implied warranties; negligence and negligent misrepresentation; fraud and misrepresentation; violation of the South Carolina Unfair Trade Practices Act; intentional infliction of emotional distress; and loss of consortium. (Compl. ¶¶ 102-206). In sum, Plaintiffs

³ Contrary to Plaintiffs’ allegation, (*see* Compl. ¶ 67), at no time did Schwarz publish a copy of its label for Reglan[®] tablets in the *Physician’s Desk Reference*. (Exh. 2, Siefert Aff. ¶ 4).

allege that Wyeth and Schwarz should be held liable for their alleged injuries because Wyeth, and then Schwarz, purportedly failed to adequately warn Mr. Fisher's physicians about the risks associated with the use of the generic metoclopramide tablets manufactured by Pliva.

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where there is no genuine issue of material fact. Fed. R. Civ. P. 56(c); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Once a party moving for summary judgment has made a sufficient showing, the non-moving party has the burden to set forth specific facts, by affidavit or other evidence, showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). In doing so, the non-moving party may not simply rest on the pleadings and allegations and "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986) ("the mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat summary judgment). Rather, to survive summary judgment, the party opposing the motion must prove there is sufficient evidence to support a jury verdict in its favor. *Anderson*, 477 U.S. at 249.

ARGUMENT

Plaintiffs' attempt to hold Wyeth and Schwarz liable for injuries caused by their competitor's drug is contrary to South Carolina law and has been rejected by all but one of the courts that have considered the issue (Section I, *infra*). Further, Plaintiffs cannot establish the specific elements of each of their claims (Section II, *infra*). Accordingly, this Court should enter judgment in favor of Wyeth and Schwarz on all claims.

I. PLAINTIFFS' CLAIMS FAIL BECAUSE NEITHER WYETH NOR SCHWARZ MANUFACTURED OR DISTRIBUTED THE PRODUCT THAT ALLEGEDLY CAUSED MR. FISHER'S INJURY.

A. South Carolina Law Limits Liability to Only the Defendant Whose Product Caused the Plaintiff's Injury.

South Carolina law bars each of Plaintiffs' claims because Plaintiffs cannot satisfy the threshold requirement of product identification. South Carolina law requires that a plaintiff seeking to recover for injuries allegedly caused by a product – regardless of the theory of liability asserted – must plead and prove that the defendant manufactured the actual product that caused the injuries. *See, e.g., Ryan*, 514 F. Supp. at 1006; *Baughman*, 627 F. Supp. at 874.

In *Ryan*, the plaintiff brought a products liability action against seven drug companies, alleging that she had developed a pre-cancerous condition as a result of her mother's ingestion of diethylstilbestrol (DES). Although the plaintiff was unable to identify which of the 118 DES manufacturers made and sold the DES ingested by her mother, she brought suit against two drug companies, one of which she believed most likely manufactured the DES taken by her mother, as well as five other drug companies for conspiracy in their production of synthetic estrogens. *Ryan*, 514 F. Supp. at 1006. She asserted claims similar to those in this case, including negligence, breach of warranties, strict liability, civil conspiracy, and fraud. In granting the defendants' motion for summary judgment, the court determined that the "major weakness" in the plaintiff's case was her inability to identify the manufacturer of the DES taken by her mother. *Id.* The court specifically stated that "It goes without saying that if a drug manufacturer... is to be held liable for harm caused by a product... it must be shown that the defendant actually manufactured, compounded, or sold the drug or medicine in question." *Id.* (quoting *Liability of Manufacturer or Seller for Injury Caused by Drug or Medicine Sold*, 79 A.L.R. 2d § 19, at 338 (1961)). Because the plaintiff "offered nothing to show that one of these seven, and not one of

the other one hundred eleven, manufacturers produced the drug in question,” the court held she was “unable to meet the threshold burden of maintaining this action i.e., identifying the manufacturer of the drug taken and thereby establishing causation in fact.” *Id.* at 1007. Accordingly, all claims were dismissed.

In *Baughman*, the plaintiff brought a products liability action against the defendant truck manufacturer after the plaintiff was injured when a tire he was installing exploded. Because the plaintiff was unable to identify the type of rim involved in the explosion, the defendant moved for summary judgment on the grounds that the plaintiff could not show that it manufactured or sold the allegedly defective tire rim. 627 F. Supp. at 873. The court granted the motion, noting that a plaintiff “must be capable of showing that the defendant either manufactured, sold or exercised control over the defective product.” *Id.* at 874.

Here, Plaintiffs’ claims against Wyeth and Schwarz, which are all premised on an alleged injury from a product, fail as a matter of this well-settled South Carolina law. Mr. Fisher did not purchase, did not ingest, and was not injured by Wyeth’s or Schwarz’s drug. Accordingly, all of their claims, however labeled, must be dismissed.

B. The Fourth Circuit Has Held That Brand Name Manufacturers Cannot Be Held Liable for Injuries Caused by Their Competitors’ Generic Products.

The novel theory advanced by Plaintiffs – that Wyeth and Schwarz as brand name Reglan[®] manufacturers are liable for injuries caused by their competitors’ generic metoclopramide – has been considered and expressly rejected by the Fourth Circuit in *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994). In *Foster*, the plaintiffs, parents of a child who died after ingesting generic promethazine, brought suit against Wyeth, the manufacturer of Phenergan[®], the brand name version of the drug. *Id.* at 167. Even though the plaintiffs conceded that only the generic drug had been ingested by their daughter, they argued

(as Plaintiffs do in this case) that brand name manufacturers like Wyeth could be held liable because they knew that physicians rely on the brand name label and that “generic manufacturers rely on their studies and duplicate their labeling.” *Id.* at 167-69. Thus, the plaintiffs argued, Wyeth was liable for their daughter’s death to the extent the warning on the generic medication was defective. *Id.*

The Fourth Circuit rejected these arguments for three separate and independent reasons. First, the court reasoned that all of the plaintiffs’ claims – regardless of the theory of liability – failed as a matter of law because Wyeth did not manufacture or sell the product that caused the alleged injuries. *Id.* at 167. In so holding, the court found that plaintiffs were *trying to disguise products liability claims as claims for misrepresentation in order to avoid the necessity of demonstrating that Wyeth manufactured the allegedly defective drug*: “the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions.” *Id.* at 168. As the *Foster* court explained:

The Fosters are attempting to hold Wyeth liable for injuries caused by another manufacturer’s product, and we are persuaded that Maryland courts would reject this effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury.

Id. In short, the Fourth Circuit held, “[r]egardless of the recovery theory,” a products liability plaintiff must establish product identification. *Id.* As explained above, this reasoning is on-point with South Carolina law. (Section I.A., *supra*).

Second, the *Foster* court concluded that no legal precedent or FDA law or regulation imposes liability on the brand name manufacturer for injuries caused by the drug of its generic competitors. *Id.* at 170. The court recognized that “[n]ame brand manufacturers undertake the

expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information.” *Id.* After reviewing FDA statutes and regulations, common law and public policy implications, the court rejected the plaintiffs’ theory of liability:

There is no legal precedent for using a name brand manufacturer’s statements about its own product as a basis for liability for injuries caused by other manufacturers’ products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer’s statements by copying its labels and riding on the coattails of its advertising. The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer’s drug has been consumed.

Id. (emphasis added). The court further commented that “[m]anufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.” *Id.* This second rationale – the absence of any legal or regulatory basis for liability – also defeats Plaintiffs’ claims.

Third, the *Foster* court concluded that Wyeth did not owe a duty to the plaintiffs to warn about the risks associated with the generic drug. The plaintiffs argued that it was “foreseeable to Wyeth that misrepresentations could . . . result in personal injury to users of . . . generic equivalents.” *Id.* at 171. The court rejected this argument, concluding that “Wyeth is under no duty of care” to consumers of other companies’ generic drugs:

We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far. The duty required . . . arises when there is such a relationship that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care. There is no such relationship between the parties to this case, as Brandy Foster was injured by a product that Wyeth did not manufacture.

Id. (internal quotations and citations omitted) (emphasis added). This final rationale – the absence of any duty – is consistent with South Carolina law. (Section II, *infra*). Because Mr. Fisher did not purchase or use Wyeth’s or Schwarz’s metoclopramide, there is no duty owed.⁴

C. Numerous Courts Have Held That Brand Name Manufacturers Cannot Be Held Liable For Injuries Caused By Generic Products.

Courts across the country have adopted the reasoning set forth in *Foster* and have rejected claims that brand name manufacturers are liable for injuries caused by their competitors’ generic drugs. Indeed, *thirty-five decisions applying the laws of twenty different states* (Alabama, Arkansas, Colorado, Florida, Georgia, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, and West Virginia) have held that a brand name manufacturer cannot be held liable for injuries caused by the ingestion of a generic manufacturer’s product.⁵ See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613 (8th Cir. 2009); *Morris v. Wyeth*, No. 3:09-cv-00854-RGJ-KLH, 2009 WL 4064103, at *2-*5 (W.D. La. Nov. 23, 2009); *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL

⁴ On November 27, 2009, the Eighth Circuit joined the Fourth Circuit in rejecting plaintiffs’ attempt to hold Wyeth and Schwarz (as former brand name manufacturers) liable for injuries caused by their competitors’ generic products. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

⁵ The *only* court to rule otherwise is a California intermediate appellate court sitting in San Francisco. See *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008), attached as Exhibit 3. However, not a single decision has followed *Conte*. Rather, eleven courts that have considered the issue since *Conte* have declined to follow its reasoning and holding. See *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722, Order at 2 (Fla. Cir. Ct. 15th Jud. Cir. Dec. 21, 2009); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613 (8th Cir. 2009); *Morris v. Wyeth*, No. 3:09-cv-00854-RGJ-KLH, 2009 WL 4064103, at *2-*5 (W.D. La. Nov. 23, 2009); *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716, at *3 (S.D.W.V. Nov. 13, 2009); *Burke v. Wyeth, Inc.*, No. G-09-00082, 2009 WL 3698480, at *2-*3 (S.D. Tex. Oct. 29, 2009); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633-34 (E.D.N.C. 2009); *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056, 1060-61 (W.D. Ark. 2009); *Moretti v. Wyeth*, No. 2:08-CV-00396, 2009 WL 749532, at *3-*4 (D. Nev. Mar. 20, 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1266-67 (W.D. Okla. 2009); *Cousins v. Wyeth Pharma, Inc.*, No. 3:08-CV-0310-N, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009); *Huck v. Trimark Physicians Group*, No. LACV018947, 2009 WL 3760458, Order at 1-2 (Iowa Dist. Ct. Feb. 27, 2009).

3806716, at *2-*4 (S.D.W.V. Nov. 13, 2009); *Burke v. Wyeth, Inc.*, No. G-09-00082, 2009 WL 3698480, at *2-*3 (S.D. Tex. Oct. 29, 2009); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633-34 (E.D.N.C. 2009); *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056, 1060-61 (W.D. Ark. 2009); *Moretti v. Wyeth*, No. 2:08-CV-00396, 2009 WL 749532, at *3-*4 (D. Nev. Mar. 20, 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1266-67 (W.D. Okla. 2009); *Cousins v. Wyeth Pharma., Inc.*, No. 3:08-CV-0310-N, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009); *Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2008 WL 2677051, at *4 (W.D. Ky. June 30, 2008); *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R, 2008 WL 2677049, at *4 (W.D. Ky. June 30, 2008); *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2008 WL 2677048, at *4 (W.D. Ky. June 30, 2008); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 1351, 1358 (N.D. Ga. 2008); *Barnhill v. Teva Pharm. USA, Inc.*, No. Civ. A. 06-0282-CB M, 2007 WL 6947996, Order at 4 (S.D. Ala. Apr. 24, 2007); *Leblanc v. Wyeth, Inc.*, No. Civ. A 04-0611, 2006 WL 2883030, at *6 (W.D. La. Oct. 5, 2006); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), *aff'd in pertinent part and rev'd in other part*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded*, 129 S. Ct. 1578 (2009), *vacated and remanded*, 06-3107 (3rd Cir. Apr. 28, 2009); *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2006 WL 1517546, at *2 (W.D. La. Jan. 26, 2006); *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2005 WL 4052382, at *2 (W.D. La. June 7, 2005); *Block v. Wyeth, Inc.*, 02-CV-1077, 2003 WL 203067, at *2 (N.D. Tex. Jan. 28, 2003); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. App. 1 Cir. 2008); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); *Sharp v. Leichus*, 04-CA-643, 2006 WL 515532, at *4 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd per curiam*, 952 So. 2d 555 (Fla. 1st Dist. Ct. App. 2007); *Dietrich v. Wyeth, Inc.*,

No. 50-2009-CA-021586, 2009 WL 4924722, Order at 2 (Fla. Cir. Ct. 15th Jud. Cir. Dec. 21, 2009); *Huck v. Trimark Physicians Group, et al.*, No. LACV018947, 2009 WL 3760458, Order at 1-2 (Iowa Dist. Ct. Feb. 27, 2009); *Buchanan v. Wyeth Pharm., Inc.*, CV-2007-900065, Order at 1 (Ala. Cir. Ct. Oct. 20, 2008); *Green v. Wyeth Pharm., Inc.*, CV-06-3917 ER, 2007 WL 6428717, Order at 1 (Ala. Cir. Ct. May 15, 2007); *Kelly v. Wyeth*, 03-CV-3314, 2005 WL 4056740, at *2 (Mass. Super. Ct. May 6, 2005); *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004); *Reynolds v. Anton*, No. 01A-76719-3, 2004 WL 5000272, at *9 (Ga. Super. Ct. Oct. 28, 2004); *Westerlund v. Wyeth, Inc.*, No. MID L02174-05, 2008 WL 5592753, Order at 3 (N.J. Super. Ct. Oct. 20, 2008); *Sloan v. Wyeth*, No. MRS-L-1183-04, 2004 WL 5767103, at *4 (N.J. Super. Ct. Oct. 13, 2004); *Beutella v. A.H. Robins Co., Inc.*, No. 05-CV-2372, 2001 WL 35669202, at *2 (Utah Dist. Ct. Dec. 10, 2001).⁶

These decisions are consistent with South Carolina law as described above.

D. Twenty-Six Decisions In Seventeen Different States Have Rejected Identical Claims Against Wyeth And/Or Schwarz In Cases Involving Metoclopramide.

A combined *twenty-six different decisions in seventeen states* have expressly held that Wyeth and/or Schwarz, as brand name Reglan[®] manufacturers, cannot be held liable for injuries allegedly caused by the ingestion of their competitors' generic metoclopramide.⁷

⁶ Copies of these opinions are attached in alphabetical order as Exhibit 4.

⁷ See *Dietrich*, 2009 WL 4924722, Order at 2; *Mensing*, 588 F.3d at 613; *Morris*, 2009 WL 4064103, at *2-*5; *Meade*, 2009 WL 3806716, at *2-*4; *Burke*, 2009 WL 3698480, at *2-*3; *Stoddard*, 630 F. Supp. 2d at 633-34; *Fields*, 613 F. Supp. 2d at 1060-61; *Moretti*, 2009 WL 749532, at *3-*4; *Schrock*, 601 F. Supp. 2d at 1266-67; *Cousins*, 2009 WL 648703, at *2; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Pustejovsky*, 2008 WL 1314902, at *2; *Swicegood*, 543 F. Supp. 2d at 1358; *Tarver*, 2005 WL 4052382, at *2; *Tarver*, 2005 WL 4052382, at *2; *Block*, 2003 WL 203067, at *2; *Sharp*, 2006 WL 515532, at *4; *Huck*, 2009 WL 3760458, Order at 1-2; *Buchanan*, Order at 1; *Green*, 2007 WL 6428717, Order at 1; *Kelly*, 2005 WL 4056740, at *2; *Sheeks*, 2004 WL 4056060, at *2; *Sloan*, 2004 WL 5767103, at *4; *Beutella*, 2001 WL 35669202, at *2.

In November 2009, the United States Court of Appeals for the Eighth Circuit reaffirmed the continuing validity of the principles set forth in *Foster*. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). Affirming summary judgment for Schwarz and Wyeth (in their capacity as former brand name manufacturers) on the plaintiff's fraud and negligent misrepresentation claims, the *Mensing* court held that "[l]ike the Fourth Circuit [in *Foster*], we conclude that holding name brand manufacturers liable for harm caused by generic manufacturers 'stretch[es] the concept of foreseeability too far.'" *Id.* at 613 (internal citation omitted). Further, the Eighth Circuit held that in order to proceed against Schwarz and Wyeth on claims for fraud or negligent misrepresentation, the plaintiff was required to show that those defendants owed her a duty of care. *Id.* Because there was no direct relationship between the plaintiff-consumer of generic metoclopramide, on the one hand, and Schwarz or Wyeth, former manufacturers of Reglan[®], on the other hand, the Eighth Circuit held that the plaintiff had not "shown that the name brand manufacturers owed her a duty of care necessary to trigger liability." *Id.* at 614.

The Eighth Circuit in *Mensing* and these other courts have systematically rejected attempts to assert strict liability, negligence, fraud, misrepresentation, and other claims against Wyeth and Schwarz when their products have not been ingested. In doing so, these courts have refused to impose liability or a duty on Wyeth and Schwarz because:

- Brand name manufacturers are only liable for injuries caused by their products, and not for the injuries caused by their competitors' generic products. *See, e.g., Mensing*, 588 F.3d at 613; *Stoddard*, 630 F. Supp. 2d at 633-34; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Pustejovsky*, 2008 WL 1314902, at *2; *Swicegood*, 543 F. Supp. 2d at 1358; *Moretti*,

2009 WL 749532, at *3-*4; *Kelly*, 2005 WL 4056740, at *2-*4; *Sharp*, 2006 WL 515532, at *2; *Sheeks*, 2004 WL 4056060, at *2; *Block*, 2003 WL 203067, at *1-*2.

- Foreseeability does not support liability of the brand name manufacturer who had no relationship with the plaintiff. *See, e.g., Mensing*, 588 F.3d at 613; *Fields*, 613 F. Supp. 2d 1056; *Sharp*, 2006 WL 515532, at *7; *Moretti*, 2009 WL 749532, at *3. In the absence of any relationship between the brand name manufacturer and the plaintiff, the imposition of liability on brand name manufacturers would extend the concept of duty “beyond reason and good sense.” *Schrock*, 601 F. Supp. 2d at 1267.

- FDA statutes and regulations establish that a brand name manufacturer is responsible for only its drug, and not responsible for generic drugs. *E.g., Mensing*, 588 F.3d at 612-13; *Schrock*, 601 F. Supp. 2d at 1266; *Swicegood*, 543 F. Supp. 2d at 1358.

- Generic manufacturers are responsible for their own drug and label. *Foster*, 29 F.3d at 170; *Mensing*, 588 F.3d at 610-11; *Schrock*, 601 F. Supp. 2d at 1266; *Swicegood*, 543 F. Supp. 2d at 1358; *Moretti*, 2009 WL 749532, at *4; *Sharp*, 2006 WL 515532, at *7.

- Wyeth’s and Schwarz’s respective warnings and labeling concerning Reglan[®] are representations about its product, and cannot form the basis for liability for injuries caused by their competitors’ generic drug. *Mensing*, 588 F.3d at 613; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Sharp*, 2006 WL 515532 at *7.

- Holding brand name manufacturers liable is unfair and contrary to good public policy. *E.g., Fields*, 613 F. Supp. 2d 1056; *Schrock*, 601 F. Supp. 2d at 1266-67; *Moretti*, 2009 WL 749532, at *4. Such liability is unduly burdensome and would deter

the research and development of new drugs. *See, e.g., Kelly*, 2005 WL 4056740, at *4-*5; *Sloan*, 2004 WL 5767103, at *4.

This Court should follow this reasoning and “join[] with other courts nationwide in rejecting the claim that the manufacturer of the branded product is liable for misrepresentation in the labeling of the generic product.” *Swicegood*, 543 F. Supp. 2d at 1358 (citing *Foster* with approval); *see also Mensing*, 588 F.3d at 613 n.8 (noting, as of the date of that decision, “[t]hirty two courts applying the laws of at least seventeen states” have found no legal precedent for holding brand name manufacturers liable for injuries caused by their competitors generic products).

To accept Plaintiffs’ claims would be contrary to South Carolina and Fourth Circuit law and the near unanimous on-point authority of other jurisdictions. Such a holding would improperly make brand name manufacturers responsible for every injury caused by equivalent products made by every generic manufacturer in the United States. Indeed, such an inequitable and illogical result would have a devastating impact on the entire pharmaceutical industry, deterring manufacturers from undertaking to research and develop new drugs or from marketing existing drugs. *See, e.g., Foster*, 29 F.3d at 170 (observing that such liability would be “especially unfair” because “the generic manufacturer reaps the benefits of the name brand manufacturer’s statements by copying its labels and riding on the coattails of its advertising”); *Sloan*, 2004 WL 5767103, at *4 (stating that “manufacturers would be less likely to develop new products if liability were imposed upon these companies for injuries wrought by products of generic manufacturers”). For these very reasons, courts have refused to extend tort law into such “new and uncharted territory.” *Block*, 2003 WL 203067, at *3; *see also Colacicco*, 432 F. Supp. 2d at 543 (rejecting the plaintiff’s invitation “to drastically expand the boundaries of

Pennsylvania tort law without precedent or policy to support his position” because “the Supreme Court of Pennsylvania would not accept this invitation”).

II. SUMMARY JUDGMENT IS APPROPRIATE BECAUSE PLAINTIFFS CANNOT ESTABLISH THE SPECIFIC ELEMENTS OF EACH OF THEIR CLAIMS.

Although South Carolina law and the *Foster* court’s holding that brand name manufacturers cannot be held liable for injuries resulting from the use of another manufacturer’s generic product easily disposes of all of Plaintiffs’ claims, summary judgment is also warranted because Plaintiffs cannot establish the specific elements of each of their claims.

A. Strict Products Liability Claims (Counts 2, 3, and 4)⁸

Plaintiffs have asserted claims for strict products liability (Count 2) (Compl. ¶¶ 110-119), strict liability for manufacturing defect (Count 3) (Compl. ¶¶ 120-128), and strict liability for design defect (Count 4) (Compl. ¶¶ 129-136). Under South Carolina’s strict liability statute, regardless of the theory of recovery asserted, the plaintiff must establish three elements: (1) that the product injured the plaintiff; (2) that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant; and (3) that the injury occurred because the product was in a defective condition unreasonably dangerous to the user. S.C. Code Ann. § 15-73-10 (Law Co-op. 2005). Because Mr. Fisher never used any product that was manufactured or sold (or “left the hands of”) Wyeth or Schwarz, Plaintiffs’ three strict liability claims fail as a matter of law.

B. Breach of Express and Implied Warranties (Counts 5 and 6)

Count 5 alleges that Wyeth and/or Schwarz breached an express warranty (Compl. ¶¶ 137-142), and Count 6 alleges that they breached implied warranties (Compl. ¶¶ 143-149). Under South Carolina law, claims for breach of warranty, whether express or implied, are proper

⁸ Plaintiffs’ first Count – for medical malpractice – has been asserted only against Defendant Pelstring, Mr. Fisher’s prescribing physician. (See Compl. ¶¶ 102-109).

only against the seller or manufacturer of an allegedly defective product. S.C. Code Ann. § 36-2-313 (express warranty); § 36-2-314 (implied warranty of merchantability); § 36-2-315 (implied warranty of fitness for a particular purpose); *see also In re Breast Implant Prod. Liab. Litig.*, 331 S.C. 540, 553, 503 S.E.2d 445, 452 (1998) (noting that under South Carolina law, “a sale must occur before an implied warranty can arise”). Because Mr. Fisher never purchased (or otherwise obtained) any product manufactured or sold by Wyeth or Schwarz, Plaintiffs cannot sustain their breach of warranty claims against these defendants.

C. Negligence (Count 7) and Negligent Misrepresentation (Count 8)

Count 7 (Compl. ¶¶ 150-155) and Count 8 (Compl. ¶¶ 156-162) seek damages under various negligence-based claims. Under South Carolina law, claims based on negligence require proof of both a duty of care owed by the defendant to the plaintiff and a breach of that duty by a negligent act or omission of the defendant. *See, e.g., Crolley v. Hutchins*, 300 S.C. 355, 387 S.E.2d 716 (Ct. App. 1989); *Shaw v. City of Charleston*, 351 S.C. 32, 567 S.E.2d 530 (Ct. App. 2002); *Hurst v. Sandy*, 329 S.C. 471, 494 S.E.2d 847 (Ct. App. 1997) (providing that, under a claim for negligent misrepresentation, two of the elements that a plaintiff must prove are that the defendant owed the plaintiff a duty of care to see that truthful information was communicated to the plaintiff, and that the defendant breached the duty by failing to exercise due care). Under South Carolina law and *Foster* (and its progeny), brand name drug manufacturers (such as Wyeth and Schwarz) do not owe any sort of duty to warn about the risks associated with another manufacturer’s product. *Foster*, 29 F.3d at 171. Absent this duty, Plaintiffs cannot pursue their claims based in negligence.

D. “Breach of Undertaking Special Duty” (Count 9)

Plaintiffs attempt to assert a claim for “Breach of Undertaking Special Duty” under Count 9. (Compl. ¶¶ 163-166). There is no such cause of action under South Carolina law. In any event, as discussed, neither Wyeth nor Schwarz owed any duty to Mr. Fisher, a consumer of generic metoclopramide manufactured by another company.

E. Fraud and Misrepresentation (Count 10), Constructive Fraud (Count 11), and Fraud by Concealment (Count 12)

Count 10 (Compl. ¶¶ 167-179), Count 11 (Compl. ¶¶ 180-185), and Count 12 (Compl. ¶¶ 186-191) seek damages under various claims based on fraud/misrepresentation. Although each theory has its own specific requirements, under South Carolina law, claims based on fraud require that the plaintiff show, among other things, that there was a special relationship between the parties such that the plaintiff had a right to rely on the alleged misrepresentation. *DeHart v. Dodge City of Spartanburg, Inc.*, 311 S.C. 135, 139, 427 S.E.2d 720, 722 (Ct. App. 1993) (“no right to rely, as required to establish fraud, where there is no confidential or fiduciary relationship”); *see also Ardis v. Cox*, 314 S.C. 512, 517, 431 S.E.2d 267, 270 (Ct. App. 1993) (same); *Florentine Corp., Inc. v. PEDAI, Inc.*, 287 S.C. 382, 386, 339 S.E.2d 112, 144 (1985) (same). Further, nondisclosure becomes fraudulent concealment only when it is the duty of the party having knowledge of the facts to make them known to the other party to the transaction. *See Pitts v. Jackson Nat’l Life Ins. Co.*, 352 S.C. 319, 574 S.E.2d 502 (Ct. App. 2002).

Here, there is no relationship between Plaintiffs and Wyeth or Schwarz given that Mr. Fisher never purchased (or otherwise obtained) any product manufactured or sold by Wyeth or Schwarz. *See Foster*, 29 F.3d at 171. Also, as previously discussed, Wyeth and Schwarz do not possess a duty to warn about the risks associated with another manufacturer’s generic product. Because failure to prove any element of fraud is fatal to the action, *Sorin Equip. Co. v. Firm*,

Inc., 323 S.C. 359, 474 S.E.2d 819 (Ct. App. 1996), Plaintiffs' claims based on fraud/misrepresentation fail as a matter of law.

F. Violation of the South Carolina Unfair Trade Practices Act (Count 13)

Count 13 asserts that Wyeth and Schwarz have violated the South Carolina Unfair Trade Practices Act. S.C. Code Ann. §§ 39-5-10 *et seq.* (Compl. ¶¶ 192-198). A violation of the South Carolina Unfair Trade Practices Act requires proof of three elements: (1) an unfair or deceptive act or practice; (2) proximate cause; and (3) damages. *Charleston Lumber Co., Inc. v. Miller Housing Corp.*, 318 S.C. 471, 458 S.E.2d 431 (Ct. App. 1995), *rev'd on other grounds*, 338 S.C. 171, 525 S.E.2d 869 (S.C. 2000). Here, Plaintiffs cannot show that a product manufactured by Wyeth or Schwarz proximately caused Plaintiffs' injuries. Accordingly, their claim for violation of the South Carolina Unfair Trade Practices Act fails.

G. Intentional Infliction of Emotional Distress (Count 14)

Under Count 14, Plaintiffs assert a claim for intentional infliction of emotional distress. (Compl. ¶¶ 199-202). To plead and prove a claim for intentional infliction of emotional distress, a plaintiff must show that (1) the defendant intentionally or recklessly inflicted severe emotional distress, or was certain, or substantially certain, that such distress would result from his conduct; (2) the conduct was "so extreme and outrageous" so as to exceed "all possible bounds of decency" and must be regarded as "atrocious, and utterly intolerable in a civilized community;" (3) the action of the defendant caused plaintiff's emotional distress; and (4) the emotional distress suffered by the plaintiff was "severe" such that "no reasonable man could be expected to endure it." *Ford v. Hutson*, 276 S.C. 157, 162, 276 S.E.2d 776, 778 (1981).

"It is for the court to determine in the first instance whether the defendant's conduct may reasonably be regarded as so extreme and outrageous as to permit recovery, and only where

reasonable persons might differ is the question one for the jury.” *Todd v. South Carolina Farm Bureau Mut. Ins.*, 283 S.C. 155, 167, 321 S.E.2d 602, 609 (Ct. App. 1984), *rev’d in part on other grounds*, 287 S.C. 190, 336 S.E.2d 472 (1985); *see also Hansson v. Scalise Builders of South Carolina*, 374 S.C. 352, 358, 650 S.E.2d 68, 72 (2007) (noting that “[i]n order to prevent claims for intentional infliction of emotional distress from becoming a panacea for wounded feelings rather than reprehensible conduct, the court plays a significant gatekeeping role in analyzing a defendant’s motion for summary judgment”) (internal quotations and citations omitted). Furthermore, under the “heightened standard of proof” for emotional distress claims, more than mere “bald assertions” are required; a party must show “something ‘more’ – in the form of third party witness testimony and other corroborating evidence – in order to make a prima facie showing of ‘severe’ emotional distress.” *Hansson*, 374 S.C. at 358-59, 650 S.E.2d at 72.

Here, Plaintiffs’ Complaint falls far short of a showing that the defendants’ conduct was “so extreme and outrageous” as to permit recovery. Plaintiffs’ Complaint does not allege that Wyeth or Schwarz intended to cause Plaintiffs emotional distress, nor does the Complaint allege that Plaintiffs suffered any actual emotional or mental disorder. Finally, because Mr. Fisher did not ingest a product manufactured by Wyeth or Schwarz, Plaintiffs cannot satisfy the element of causation. Because Plaintiffs completely fail to indicate how the defendants’ alleged conduct was “so extreme and outrageous” as to exceed “all possible bounds of decency,” their claim for intentional infliction of emotional distress fails as a matter of law.

H. Loss of Consortium (Count 15)

Under Count 15, Mrs. Fisher asserts a claim for loss of consortium. (Compl. ¶¶ 203-206). South Carolina law provides that a loss of consortium claim is considered separate and distinct from the injured spouse’s claim for personal injuries. *See Daves v. Cleary*, 355 S.C. 216, 231,

584 S.E.2d 423, 430 (Ct. App. 2003). However, “[g]enerally, a plaintiff spouse’s claim for loss of consortium fails if the impaired spouse’s claim fails, whether the claim is considered separate and independent from the impaired spouse’s claim or derivative in nature.” *Lee v. Bunch*, 373 S.C. 654, 663, 647 S.E.2d 197, 202 (2007); *see also Smith v. Ridgeway Chem., Inc.*, 302 S.C. 303, 395 S.E.2d 742 (Ct. App. 1990) (holding husband could not recover on loss of consortium because the jury found that the wife was not entitled to recover on her strict liability claim). Because Mr. Fisher cannot establish the specific elements of each, much less any, of the claims asserted in the Complaint, Mrs. Fisher’s claim for loss of consortium also must fail as a matter of law.

CONCLUSION

Given the undisputed fact that Plaintiffs did not purchase or ingest any product that was manufactured or sold by Wyeth or Schwarz, and that South Carolina and Fourth Circuit law explicitly rejects Plaintiffs’ broad theories of recovery, Wyeth and Schwarz respectfully request that the Court grant summary judgment and enter judgment on all claims in their favor.

Respectfully submitted,

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